

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In:re the Application of James F. McBride, et al.

Group Art Unit: 1615 (Anticipated)

Application No.: Divisional of 09/576,714, filed May 23, 2000

Examiner: Charesse L. Evans (Anticipated)

Filed: Herewith

Docket No.: 12013/52003

For: TEMPERATURE CONTROLLED SOLUTE DELIVERY SYSTEM

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 CFR § 1.56, the attention of the Patent and Trademark Office is hereby directed to the reference(s) listed on the attached PTO-1449. Unless otherwise indicated herein, one copy of each reference is attached. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the reference(s) be made of record therein and appear among the "References Cited" on any patent to issue therefrom. The filing of this Information Disclosure Statement and the enclosed PTO Form No. 1449, shall not be construed as an admission that the information cited is prior art, or is considered to be material to patentability as defined in 37 C.F.R. § 1.56(b). The paragraphs marked below are applicable. It is believed that no fees other than those indicated below are due, but authorization is hereby given to charge any additional fees due, or to credit any overpayment, to deposit account 11-0600.

1. This Information Disclosure Statement is being filed (a) within three months of the filing date of a national application other than a continued prosecution application under 37 C.F.R. §1.53(d), (b) within three months of the date of entry of the national stage as set forth in 37 C.F.R. § 1.491 in an international application, (c) before the mailing date of a first Office Action on the merits in the present application, OR (d) before the mailing of a first office action after filing of a request for continued examination. No certification or fee is required.

☐ 2. This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a final action, Notice of Allowance, or any action that otherwise closes prosecution.

☐ a. I hereby certify that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 CFR §1.97(e)(1).

☐ b. I hereby certify that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 CFR §1.97(e)(2).

☐ c. Please debit Deposit Account No. 11-0600 in the amount of \$180.00 in payment of the fee under 37 CFR §1.17(p) to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached. 37 CFR §1.97(c)(2).

☐ 3. This Information Disclosure Statement is being filed after the mailing date of a final action, Notice of Allowance or an action that otherwise closes prosecution, but before payment of the Issue Fee. Applicant(s) hereby request(s) that the Information Disclosure Statement be considered. Please debit Deposit Account No. 11-0600 in the amount of \$180.00 in payment of the petition fee under 37 CFR §1.17(p) to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached.

☐ a. I hereby certify that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in any counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 CFR §1.97(e)(1).

☐ b. I hereby certify that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 CFR §1.97(e)(2).


☐ 4. Relevance of the non-English language reference(s) is discussed in the present specification.

- ☐ 5. The reference(s) was/were cited in a counterpart foreign application. An English language version of the foreign search report is attached for the Examiner's information.
- ☐ 6. A concise explanation of the relevance of the non-English language reference(s) appears in the Appendix attached hereto.
- ☐ 7. The Examiner's attention is directed to co-pending U.S. Patent Application No. _____, filed, which is directed to related technical subject matter. The identification of this U.S. Patent Application is not to be construed as a waiver of secrecy as to that application now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination of the present application.
- ☐ 8. This application is one of a series of related applications, identified in the attached Appendix, which are directed to related technical subject matter. The identification of those U.S. Patent Applications is not to be construed as a waiver of secrecy as to those applications now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited applications and the art cited therein during the examination.
- ☒ 9. The reference(s) was/were cited by or submitted to the Office in parent application No. 09/576,714, filed May 23, 2000, which is relied upon for an earlier filing date under 35 U.S.C. §120. Thus, copies of these references are not attached. 37 CFR §1.98(d).
- ☐ 10. English-language Abstracts of the non-English language references are attached hereto.
- ☐ 11. Since this application was filed after June 30, 2003, copies of U.S. references are not included.
- ☐ 12. Other.

Respectfully submitted,

KENYON & KENYON

Date: 2/27/07



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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 4

Complete if Known

Application Number	Unassigned
Filing Date	Herewith
First Named Inventor	James F. McBride, et al.
Art Unit	1615 (Anticipated)
Examiner Name	C. L. Evans (Anticipated)
Attorney Docket Number	12013/52003

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
		US- 4,481,323	11/06/84	Sterling	
		US- 4,515,593	05/07/85	Norton	
		US- 4,589,873	05/20/86	Schwartz et al.	
		US- 4,603,152	07/29/86	Laurin et al.	
		US- 4,769,013	09/06/88	Lorenz et al.	
		US- 4,830,855	05/16/89	Stewart	
		US- 4,912,032	03/27/90	Hoffman et al.	
		US- 4,950,256	08/21/90	Luther et al.	
		US- 5,000,955	03/19/91	Gould et al.	
		US- 5,026,607	06/25/91	Kiezulas	
		US- 5,041,100	08/20/91	Rowland e al.	
		US- 5,091,205	02/25/92	Fan	
		US- 5,102,402	07/07/92	Dror et al.	
		US- 5,135,516	08/04/92	Sahatjian et al.	
		US- 5,417,983	05/23/95	Nagase et al.	
		US- 5,525,348	06/11/96	Whitbourne et al.	
		US- 5,580,573	12/03/96	Kydnieus et al.	
		US- 5,652,225	07/29/97	Isner	
		US- 5,674,192	10/07/97	Sahatjian et al.	
		US- 5,171,217	12/15/92	March et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
		UK 2 112 646	07/27/83			
		EP 0 379 156 A2	07/25/90			
		WO 91/08790	06/27/91			
		EP 0 177 983	04/1986			
		WO 98/02114	01/22/98			
		WO 98/46287	10/22/98			

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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Sheet 2 of 4

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		Number - Kind Code ² (if known)			
		US- 5,932,248	08/03/99	Chen et al.	
		US- 5,603,955	02/1997	S. H. Gehrke et al.	
		US- 5,840,338	11/1998	E, H, Roos	
		US- 5,304,121	04/19/94	Sahatjian	
		US- 5,152,758	10/06/92	Kaetsu et al.	
		US- 5,674,521	10/1997	S. H. Gehrke et al.	
		US- 5,607,417	03/04/97	Batich et al.	
		US- 5,516,808	05/14/96	Sawaya	
		US- 5,221,698	06/22/93	Amidon et al.	
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Sheet 3 of 4

Complete if Known

Application Number	Unassigned
Filing Date	Herewith
First Named Inventor	James F. McBride, et al.
Art Unit	1615 (Anticipated)
Examiner Name	C. L. Evans (Anticipated)
Attorney Docket Number	12013/52003

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		McBride et al., M. S. Thesis, 1996.	
		Y. Osada et al., Intelligent Gels, Scientific American, May 1993.	
		Anna Gutowska et al., Journal of Biomedical Materials Research, 1995, "Heparin release from thermosensitive polymer coatings: In vivo studies", Vol. 29, pp. 811-821.	
		Hsieh, D., "Controlled Release Systems: Fabrication Technology," Vol. II, 1988.	
		Gehrke, S., Lyu, L-H, Barnhouse, C., "Dewatering Fine Coal Slurries by Gel Extraction," Separation Science and Technology, 33(10), pp. 1467-1485, 1998.	
		Kabra, B., Gehrke, S H., and Spontak, R.J., "Microporous, Responsive Hydroxypropyl Cellulose Gels. 1. Synthesis and Microstructure," Macromolecules, Vol. 31, No. 7, Pages 2166-2173 (1998).	
		Bae et al., "Thermo-sensitive polymers as on-off switches for drug release," Makromol. Chem. Rapid Commun..., 1987, 8:481-485.	
		Bae, "Stimuli-Sensitive Drug Delivery, <u>"CONTROLLED DRUG DELIVERY: Challenges and Strategies</u> , 147-162, American Chemical Society, Washington D.C., 1997.	
		Gehrke et al., "Factors Determining Hydrogel Permeability, <u>"BIOARTIFICIAL ORGANS: Science, Medicine and Technology</u> , Annals of the New York Academy of Sciences, 1997, 831:179-206.	
		McBride, "Solute Permeability and Release from Thermosensitive Gels," Master of Science Thesis, University of Cincinnati, Division of Research and Advanced Studies, 1996.	
		Yoshida et al., "Drug Release Profiles in the Shrinking Process of Thermoresponsive Poly(N-isopropylacrylamide-co-alkyl methacrylate) Gels," Ind. Eng. Chem. Res., 1992, 31:2339-2345.	

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				Art Unit	1615 (Anticipated)
				Examiner Name	C. L. Evans (Anticipated)
Sheet	4	of	4	Attorney Docket Number	12013/52003

NON PATENT LITERATURE DOCUMENTS			
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		Gutowska et al., "Thermosensitive Interpenetrating Polymer Networks: Synthesis, Characterization, and Macromolecular Release," Macromolecules, 1994, 27:4167-4175.	
		Dinarvand et al., "The use of thermoresponsive hydrogels for on-off release of molecules." Journal of Controlled Release, 1995, 36:221-227.	
		Harsh et al., "Controlling the swelling characteristics of temperature-sensitive cellulose ether hydrogels," Journal of Controlled Release, 1991, 17:175-186.	
		Gehrke et al., "Effect of Synthesis Conditions on Properties of Poly(N-isopropylacrylamide) Gels," Polymer International, 1992, 29:29-36.	
		Fram et al., "Localized Intramural Drug Delivery During Balloon Angioplasty Using Hydrogel-Coated Balloons and Pressure-Augmented Diffusion," J. Am. Coll. Cardiol., 1994, 23:1570-1577.	
		Gutowska et al., "Heparin release from thermosensitive polymer coatings: In vivo studies," J. Biol. Materials Research, 1995, 29:811-821.	
		Fram et al., "Localized Intramural Delivery of a Marker Agent During Balloon Angioplasty: A New Technique Using Hydrogel-Coated Balloons and Active Diffusion," Abstracts From the 65 th Scientific Session, October 1992, Supplement I, 86/4:1-380, Abstract 1515.	
		Nunes et al., "HYDROGEL-COATED PTC BALLOON CATHETER DELIVERY OF AN ANTITHROMBIN INHIBITS PLATELET-DEPENDENT THROMOSIS," Abstracts From the 65 th Scientific Session, October 1992, Supplement I, 86/4:1-380, Abstract 1516.	
		Fisher, "The Permeability of Temperature Responsive Cellulose Ether Hydrogels," Master of Science Thesis, University of Cincinnati, Division of Research and Advanced Studies, 1997.	

Examiner Signature		Date Considered	
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